

REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 1-6, 8-44, and 61-63 are pending in this application.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-6, 8-44, and 61-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. (U.S. Patent No. 6,419,952) in view of Dong et al. (U.S. Patent No. 5,800,422). This rejection is respectfully traversed.

A prima facie case of obviousness is made out when at least one value in the claimed range is shown by the prior art. *Haynes Int'l, Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n.3, 28 USPQ2d 1652, 1655 n.3 (Fed. Cir. 1993). "One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F. 3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). Unexpected results must be factual evidence. "Mere argument or conclusory statements in the specification does not suffice." *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1994).

In the remarks filed on June 5, 2006, applicant showed factually that the combination of claimed ranges in Claim 1 exhibits unexpected results and is not disclosed in Wong et al. In the office action dated July 14, 2006, the Examiner states: "Applicants' arguments have been fully considered and are persuasive. The showing that a particular ratio of osmagent to osmopolymer allows dry formulation without cracking is unexpected considering the teachings of Wong." The Examiner then asserts that Dong et al. teach a different ratio of osmopolymer to osmagent and a dry coating process in Example 1 and does not report any cracking. The Examiner further asserts that since Dong et al. do not report any cracking, the results cannot be said to be unexpected when Dong's teachings are considered. The Examiner further asserts that to the

extent that the amounts of materials required are somewhat different from those of instant claims, the difference is deemed to be merely optimization.

Applicant contends that reliance on the teachings of Dong et al. to determine whether or not there is any cracking in the osmotic layer of Dong et al. is improper since Dong et al. have not provided any cracking studies of their dosage forms. Moreover, the osmotic layers of Wong et al. and Dong et al. are based on different solvent systems. Wong et al. teach a two-part solvent system in Examples 1, 4, and 8, whereas Dong et al. teach a one-part solvent system in Example 1. The Examiner in combining Wong et al. with Dong et al. seems to be suggesting that cracking characteristics of an osmotic layer based on a one-part solvent system are the same as that of an osmotic layer based on a two-part solvent system. However, this position is unsupportable based on the disclosure of Wong et al. and Dong et al. Therefore, even if the disclosed film former/osmopolymer/osmotic agent ratios in the osmotic layer of Dong et al. do not exhibit cracking in a one-solvent system, this does not preclude that these same film former/osmopolymer/osmotic agent ratios will not exhibit cracking in a two-part solvent system. In addition, Dong et al. disclose an osmopolymer to osmotic agent ratio of 1.96:1. This is clearly outside of the range recited in claim 1. Thus, Dong et al. do not overcome the deficiency in Wong et al.

As stated above, a prima facie case of obviousness made out when at least one value in the claimed range is shown by the prior art can be rebutted by making a factual showing of unexpected results in the claimed range. The criticality of the combination of claimed ranges recited in claim 1 was demonstrated factually in the remarks filed on June 5, 2006. This combination of claimed ranges is not disclosed by or obvious in view of Wong et al. This combination of claimed ranges is also not disclosed by or obvious in view of Dong et al., considering particularly that the osmotic layer in Dong et al. is based on a one-part solvent system whereas the coating suspension for an osmotic layer recited in claim 1 of the instant application is based on a two-part solvent system. Therefore, to the extent that Wong et al. is combinable with Dong et al., claim 1 is not obvious over Wong et al. in view of Dong et al. Withdrawal of the rejection of claim 1 over Wong et al. in view of Dong et al. is respectfully requested. Claims 2-6 and 8-44, being dependent from claim 1, are likewise patentable in view of the foregoing arguments. Claims 61-63 recite a method of making a dosage form using the coating suspension of claim 1 and are patentable in view of the foregoing arguments.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated July 14, 2006, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC3162R1).

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Respectfully submitted,

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